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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

GARY ZIEROTH, as representative of the estate of SHARON ZIEROTH, Plaintiff, v. ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, Defendant.	Case No. 3:20-cv-172 (MMC) **NOTICE OF MOTION AND CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

The estate of Sharon Zieroth seeks reimbursement for $4,257 in supplies for her continuous glucose monitor. Acting for the Secretary of Health and Human Services, the Medicare Appeals Council denied coverage in accordance with CMS Ruling 1682-R. Mrs. Zieroth's estate argues that CMS Ruling 1682-R was procedurally flawed, and that the Council's decision was substantively invalid. But the procedural argument was waived when it was not asserted in the administrative process, and the substantive argument is incorrect: it was neither arbitrary nor unlawful for the Secretary to determine that continuous glucose monitors accurate enough to replace a blood glucose monitor would be covered by Medicare, while less accurate devices would not. The decision of the Medicare Appeals Council should be affirmed.

BACKGROUND

A. Medicare Part B and CMS Ruling 1682-R

Medicare is a federal health insurance program for the elderly and disabled, *see* 42 U.S.C. § 1395 *et seq.*, which is administered on behalf of the Secretary of Health and Human Services by the Centers for Medicare & Medicaid Services (CMS). Part A of the Medicare statute "covers medical services furnished by hospitals and other institutional care providers." *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011) (citing 42 U.S.C. §§ 1395c to 1395i-5). Medicare Part B "is an optional supplemental insurance program that pays for medical items and services not covered by Part A, including outpatient physician services" and "durable medical equipment," among other things. *Id.* (citing 42 U.S.C. §§ 1395j to 1395w-4).

The statutory definition of durable medical equipment (DME), codified at 42 U.S.C. § 1395x(n), "includes iron lungs, oxygen tents, hospital beds, and wheelchairs . . . used in the patient's home," as well as "blood-testing strips and blood glucose monitors for individuals with diabetes" among other specified items. A regulation elaborates that durable medical equipment is "equipment[] furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

42 C.F.R. § 414.202. Such equipment is only covered by Medicare Part B if it is "reasonable

and necessary for the diagnosis or treatment" of a beneficiary's "illness or injury." 42 U.S.C. § 1395y(a)(1)(A). And the Secretary has the authority to "establish and implement quality standards for suppliers of items and services" covered by Medicare Part B. *Id.* § 1395m(a)(20).

In 2017, the Secretary issued a CMS Ruling—a "statement of policy or interpretation" that is "binding on all CMS components," 42 C.F.R. § 401.108; *see id.* § 405.1063(b)—on the subject of Part B coverage for continuous glucose monitors. CGMs measure glucose levels in the interstitial fluid between patients' cells, not in their blood. CMS Ruling 1682-R at 6; AR 558. The CMS Ruling said that some continuous glucose monitors were accurate enough to replace a blood glucose monitor, because they could be used to guide treatment decisions "such as changing one's diet or insulin dosage based solely on the readings of the CGM." *Id.* at 7; AR 559. These highly accurate CGMs are covered as durable medical equipment under the terms of the CMS Ruling, *id.* at 8; AR 560, but less accurate devices are not, *id.* at 15; AR 567.

B. Medicare Coverage Determination and Claim Appeal Process

To seek reimbursement for the cost of a continuous glucose monitor or anything else, "a Medicare Part B beneficiary must submit a claim for an 'initial determination' of whether 'the items and services are covered or otherwise reimbursable.'" *Porzecanski v. Azar*, 943 F.3d 472, 475–76 (D.C. Cir. 2019) (quoting 42 C.F.R. § 405.920); *see* 42 U.S.C. § 1395ff(a)(1). "Initial coverage determinations are made by" Medicare administrative contractors hired by the agency "to manage the preliminary claims administration process." *Porzecanski*, 943 F.3d at 476. "If the contractor denies the beneficiary's claim," he may "obtain a 'redetermination' from the same contractor." *Id.* (citing 42 U.S.C. § 1395ff(a)(3)(A); 42 C.F.R. § 405.940). "If unsuccessful, the beneficiary can seek 'reconsideration' by a 'qualified independent contractor' who is wholly independent of the initial determination contractor." *Id.* (citing 42 U.S.C. § 1395ff(c)(1)–(2); 42

C.F.R. § 405.960).

If the beneficiary remains unsatisfied, subject to a minimum amount-in-controversy requirement, "he can request a hearing before an administrative law judge (ALJ)." *Id.* (citing 42 C.F.R. § 405.1000); *see* 42 U.S.C. § 1395ff(b)(1)(E). After that, he can seek review by the Medicare Appeals Council, *see* 42 C.F.R. § 405.1100, which makes the final decision for the Secretary, *id.* § 405.1130. If the beneficiary is not satisfied with the decision of the Council, he may then seek judicial review within 60 days, 42 U.S.C. § 405(g), subject to another amount-in-controversy requirement, *id.* § 1395ff(b)(1)(E).

C. Procedural Background

Sharon Zieroth sought reimbursement by Medicare Part B for continuous glucose monitor sensors she received on three occasions in 2017 and 2018. The initial determinations and redeterminations were unfavorable, AR 787, 856, 1672; AR 548, 1665, 2099, as were the decisions on reconsideration, AR 493, 1274, 2087. Mrs. Zieroth sought review by an administrative law judge, who found her continuous glucose monitor to be a covered device. AR 48–52.

The Medicare Appeals Council undertook review on its own motion. AR 38. Before the Appeals Council, Mrs. Zieroth argued that her continuous glucose monitor should be covered under the terms of CMS Ruling 1682-R and that, to the extent the Ruling held otherwise, it was contrary to the statute and regulations. AR 20–31. Mrs. Zieroth did not challenge the procedural validity of the Ruling. *See* AR 20–35. The Appeals Council found that CMS Ruling 1682-R required it to deny coverage. AR 4–14. Mrs. Zieroth sought timely judicial review, and her estate has maintained the suit after her death.

ARGUMENT

A. The procedural objection to CMS Ruling 1682-R has been waived.

Plaintiff first suggests that CMS Ruling 1682-R was issued in violation of the Medicare Act's notice-and-comment requirement, *see* 42 U.S.C. § 1395hh(a)(2), and that the decision of the Appeals Council was therefore tainted by its reliance on a procedurally invalid CMS Ruling. But any objection to the procedural validity of CMS Ruling 1682-R was waived when it was not raised before the Appeals Council. *Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010) ("A party forfeits arguments that are not raised during the administrative process.").

And even if this Court were to reach the waived argument and rule against the Secretary, that ruling would not lead to the principal relief that plaintiff appears to be seeking: an order that the Secretary approve Mrs. Zieroth's claim for benefits. If the Secretary's final decision improperly relied on a procedurally invalid CMS Ruling, then the remedy is a remand so that the Secretary can decide Mrs. Zieroth's claim without reference to the disputed Ruling. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014) (citing *Sec. & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 201 (1947) ("After the remand was made, therefore, the Commission was bound to deal with the problem afresh, performing the function delegated to it by Congress.")). Any procedural failing in the decision of the Appeals Council should not lead to a substantive reversal.

B. The Appeals Council's decision was substantively valid.

Following CMS Ruling 1682-R, the Medicare Appeals Council determined that Mrs. Zieroth's continuous glucose monitor was not sufficiently accurate to be covered as durable medical equipment under Medicare Part B. Under the terms of that Ruling, CGMs are only covered if they are accurate enough to be "used for making diabetes treatment decisions, such as

changing one's diet or insulin dosage based solely on the readings of the CGM." AR 559. Less accurate CGMs are not covered. This determination is neither arbitrary nor contrary to statute.

To begin with, it is not contrary to statute because, despite Plaintiff's creative interpretation, a continuous glucose monitor is not a "blood glucose monitor," which the Medicare Act defines as durable medical equipment. 42 U.S.C. § 1395x(n). As CMS Ruling 1682-R explains, CGMs measure glucose levels in the interstitial fluid between patients' cells, not in their blood. AR 558. Plaintiff argues that because "glucose levels in interstitial fluid are correlated with glucose levels in the blood itself," "a measurement of interstitial glucose is [therefore] an indirect measurement of blood glucose." Mot. at 19. This argument founders on the plain statutory text.

Congress has determined that "blood-testing strips and blood glucose monitors for individuals with diabetes" should be covered as durable medical equipment. 42 U.S.C. § 1395x(n). "[B]lood-testing strips" are the supplies for a patient's "blood glucose monitor," a device that monitors glucose levels in the patient's blood. Continuous glucose monitors simply do not do so. Instead, they measure something correlated with the level of glucose in a patient's blood (that is, the level of glucose in their interstitial fluid). To the extent that there is any ambiguity in the statutory phrase, the Secretary's interpretation—that blood glucose monitors must monitor blood glucose levels, not the levels of glucose in other bodily fluids, even if they are correlated to blood glucose levels—is plainly reasonable and therefore entitled to this Court's deference. *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984).

Plaintiff next argues that it was arbitrary or otherwise unlawful for the Secretary to distinguish between continuous glucose monitors that are accurate enough to be "used for making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely

on the readings of the CGM," which are covered under the terms of CMS Ruling 1682-R, AR 559, and less accurate devices, which are not covered. Mot. at 13–17. But the Medicare Act provides the Secretary with the authority to "establish and implement quality standards for suppliers of items and services" covered by Medicare Part B. 42 U.S.C. § 1395m(a)(20). And in defining "durable medical equipment," the Act provides that coverage of certain items will be "determined under standards established by the Secretary." *Id.* § 1395x(n). CMS Ruling 1682-R sets out a coverage standard under which more accurate CGMs are covered, and less accurate CGMs are not. That determination is reasonable, lawful, and entitled to deference from this Court.

Nonetheless, as the Secretary has previously noted, he is currently reconsidering his position on whether devices such as the continuous glucose monitor at issue here should be considered durable medical equipment within the meaning of the Medicare statute and regulations. If the Secretary takes action on his reconsideration, he will promptly inform the Court.

CONCLUSION

The Court should uphold the decision of the Medicare Appeals Council, enter summary judgment in favor of the Secretary, and deny Plaintiff's motion for summary judgment.

Respectfully submitted this 3rd day of August, 2020,

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